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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Henry J. Pepin Confirmation No.: 1495
Serial No.: 10/034,697 Examiner: R. Maiorino
Filing Date: December 27, 2001 Group Art Unit: 3763
Docket No.: 1001.1460101 Customer No.: 28075
For: CATHETER INCORPORATING A CURABLE POLYMER LAYER TO
CONTROL FLEXIBILITY AND METHOD OF MANUFACTURE

TRANSMITTAL SHEET

Mail Stop Appeal Brief - Patents
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By Kathleen L. Boekley
Kathleen L. Boekley

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CLAIMS AS AMENDED							
	(3)	(4)	(5)	SMALL ENTITY		OTHER	
	REMAINING CLAIMS	HIGHEST PAID	EXTRA	RATE	ADD'L FEE	RATE	ADD'L FEE
TOTAL CLAIMS	-	=		X 9=	\$	X 18=	\$
INDEPENDENT CLAIMS	-	=		X 43=	\$	X 86 =	\$
() FIRST MULTIPLE DEPENDENT CLAIM				+ 145 =	\$	+ 290 =	\$
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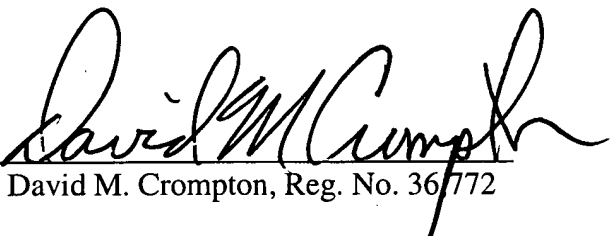
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[] Small entity status of this application under 37 C.F.R. §§ 1.9 and 1.27 has been established.

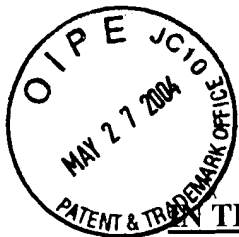
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Henry J. Pepin Confirmation No.: 1495
Serial No.: 10/034,697 Examiner: R. Maiorino
Filing Date: December 21, 2001 Group Art Unit: 3763
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Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certified that this paper or papers, as described herein are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of: EV 315614140 US, in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of May 2004.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 1.192, Appellant hereby submits this Appeal Brief in triplicate in furtherance of the Notice of Appeal filed on March 29, 2004. Enclosed herewith is a check in the amount of \$330.00 to cover the fee prescribed by 37 C.F.R. § 1.17(c). Permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, Minnesota 55311. An assignment from the inventor Henry J. Pepin conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 012432, Frame 0834.

II. RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's legal representatives, nor assignee know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-3 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Ferrera et al. (U.S. Patent No. 6,240,231). Claims 1 and 4-6 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Derbin et al. (U.S. Patent No. 6,562,021). Claims 1-6 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Berg et al. (U.S. Patent No. 5,897,537). Claims 7-10 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Ferrera et al. (U.S. Patent No. 6,240,231), Derbin et al. (U.S. Patent No. 6,562,021), or Berg et al. (U.S. Patent No. 5,897,537). The Appellant hereby appeals the final rejection of all pending claims 1-10.

IV. STATUS OF AMENDMENTS

An Amendment After Final was mailed on January 30, 2004 in response to the Final Office Action mailed December 1, 2003. An Advisory Action was mailed on February 20, 2004, in which the rejections of claims 1-10 were sustained. In the Advisory Action, the Examiner

indicated that the Amendment After Final mailed on January 30, 2004 will be entered for purposes of Appeal.

V. SUMMARY OF INVENTION¹

The invention relates to catheters or, more particularly, catheter shafts with improved designs. The inventive catheter shafts typically include an inner member (please see, for example, page 4, lines 18-21) having a plurality of layers disposed thereon. At least one of the layers includes a selectively curable material (please see, for example, page 6, lines 3-7). One or more selectively curable portions may be disposed along the catheter shaft (please see, for example, page 6, line 21 through page 7, line 4). Embodiments that include multiple selectively curable portions may have different flexibilities corresponding with the different selectively curable portions (please see, for example, page 7, lines 5-10). The different flexibilities among the selectively curable portions are dependent on the degree to which a particular selectively curable portion is cured (please see, for example, page 7, lines 5-10). For example, one selectively curable portion may be cured for a different amount of time than another selectively curable portion so that the two regions have differing flexibilities.

Turning now to the pending claims, claim 1 recites a support member used to form at least a portion of a catheter shaft comprising an inner member (Figures 1-9, reference number 12) defining an outer surface thereon (Figures 2 and 4-9, reference number 20) and a first layer (Figures 2 and 4-9, reference number 22) disposed over at least a portion of the outer surface of the inner member. Claim 1 goes on to recite that the first layer includes a selectively curable material (please see, for example, specification at page 10, lines 3-6), the first layer further

¹ The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

comprising first and second portions of the selectively curable material (Figure 3, reference numbers 32 and 34 represent first and second curable regions; please see, for example, specification at page 11, line 19 through page 12, line 2). The first portion of the selectively curable material is at least partially cured and has a first flexibility (please see, for example, specification at page 13, lines 6-9). The second portion of the selectively curable material is either uncured or cured to a lesser degree than the first portion of the selectively curable material and has a second flexibility that is different from the first flexibility (please see, for example, specification at page 12, line 16 through page 13, line 14).

Claim 2, which depends from claim 1, further recites that the first layer comprises epoxy (please see, for example, specification at page 10, lines 3-6).

Claim 3, which depends from claim 2, further recites that the first layer is ultraviolet-curable (please see, for example, specification at page 10, lines 3-6).

Claim 4, which depends from claim 1, further recites that the support member further comprises a second layer (Figures 2 and 6-9; reference number 24) disposed over at least a portion of the first layer, wherein the second layer includes a first wire ribbon (please see, for example, specification at page 10, lines 17-19).

Claim 5, which depends from claim 4, further recites that the first wire ribbon is wound in a helical pattern in a first direction (please see, for example, specification at page 10, lines 19-20).

Claim 6, which depends from claim 5, further recites that the support member further comprises a third layer (Figures 2 and 7-9, reference number 26) disposed over at least a portion of the second layer and that the third layer includes a selectively curable material (please see, for example, specification at page 10, line 22 through page 11, line 2), the selectively curable

material at least partially cured at desired portions thereof to alter the flexibility of the support member at the desired portions (please see, for example, specification at page 10, line 22 through page 11, line 2; specification at page 11, lines 12-18).

Claim 7, which depends from claim 6, further recites that the third layer is an ultraviolet-curable epoxy (please see, for example, specification at page 10, line 22 through page 11, line 2).

Claim 8, which depends from claim 6, further recites that the support member further comprises a fourth layer (Figures 2 and 8-9, reference number 28) disposed over at least a portion of the third layer and that the fourth layer comprises a second wire ribbon (please see, for example, specification at page 11, lines 3-8).

Claim 9, which depends from claim 8, further recites that the second wire ribbon is wound in a helical pattern in a second direction opposite the first direction (please see, for example, specification at page 11, lines 3-8).

Claim 10, which depends from claim 8, further recites that the support member further comprises a fifth layer (Figures 2 and 9, reference number 30) disposed over at least a portion of the fourth layer, wherein the fifth layer comprises a polymer (please see, for example, specification at page 11, lines 9-11).

VI. ISSUES

1. Whether claims 1-3 are unpatentable under 35 U.S.C. §102(e) for being anticipated by Ferrera et al. (U.S. Patent No. 6,240,231).

2. Whether claims 1 and 4-6 are unpatentable under 35 U.S.C. §102(e) for being anticipated by Derbin et al. (U.S. Patent No. 6,562,021).

3. Whether claim 1-6 are unpatentable under 35 U.S.C. §102(b) for being anticipated by Berg et al. (U.S. Patent No. 5,897,537).

4. Whether claims 7-10 are unpatentable under 35 U.S.C. 103(a) over Ferrera et al. in view of Derbin et al. or Berg et al.

VII. GROUPING OF CLAIMS

Pursuant to 37 C.F.R. § 1.192(c)(7), Appellant asserts that claims 1-10 stand or fall together.

VIII. ARGUMENT

A. Claims 1-3 are patentable over Ferrera et al. (U.S. Patent No. 6,240,231).

Two structural elements are recited in Appellant's claim 1:

an inner member defining an outer surface thereon; and
a first layer disposed over at least a portion of the outer surface of the inner member, the first layer including a selectively curable material, the first layer further comprising first and second portions of the selectively curable material;

Importantly, the second element recites a layer that includes a selectively curable material. According to page 10, lines 5-6 of Appellant's specification, an example of a selectively curable material is an ultraviolet-curable epoxy. Of course, other selectively curable materials are also contemplated.

Claim 1 goes on to recite a series of elements that modify the first layer. The first element is:

wherein the first portion of the selectively curable material is at least partially cured and the second portion of the selectively curable material is either uncured or cured to a lesser degree than the first portion of the selectively curable material.

Thus, claim 1 recites the first portion of the selectively curable material includes two structurally distinct portions. Each of the two structurally distinct portions includes a curable material that is cured to a different extent. The word “cured” as recited in claim 1 is not intended to be a verb (suggesting that the claim is to a method or the product of a method) but, instead, an adjective (suggesting that the claim is to a structure). In fact, it is common in the English language for a participle (i.e., a verb formed when the letters “ed” are added at the end of the verb so as to change the use of the word from that of a verb to that of an adjective) to be used as adjectives. Adjectives, of course, modify nouns and identify a structural distinction.

Claim 1 does not specify method steps or the product of a series of method steps. Instead, claim 1 specifies structurally distinct first and second portions. The first and second portions are structurally distinct based on the structural differences achieved by differential levels of curing. The effect of the structural changes within the selectively curable material is described at page 10, lines 10-16 of the specification:

In an exemplary embodiment, an ultraviolet-curable epoxy is understood to be an epoxy that undergoes a physical change, for example, it becomes cured when exposed to ultraviolet light. According to a preferred embodiment of the current invention, curing is understood to be the process of preparing, preserving, or finishing a substance by a chemical or physical means. Preferably, curing alters the physical properties of a substance. In a preferred embodiment, curing ultraviolet-curable epoxy alters the stiffness of catheter shaft 10.

Thus, Appellant is claiming a layer of material that has structurally distinct first and second portions that are differentiated by their respective physical characteristics. In order to clarify this line of reasoning, it may be useful to create an analogy to the organization of claim 1. For example, the claimed structural differences between the first portion and the second portion could be thought of as being analogous to ice and water. Clearly, ice and water are structurally distinct. Using this analogy, Appellant is claiming a device having a first “water” portion and a

second “ice” portion. Appellant is not attempting to claim the process of freezing the “water” portion in order to create the “ice” portion or the product resulting from the process of freezing the “water” portion.

In addition to these structural elements, claim 1 adds claim elements regarding flexibility:

wherein the first portion of the selectively curable material has a first flexibility and the second portion of the selectively curable material has a second flexibility; and

wherein the first flexibility and second flexibility are different.

Thus, not only are the first and second portion physically different based on the amount of curing each portion has undergone, they also have different flexibilities. In summary, claim 1 is structural in nature and includes a number of structural elements.

Ferrera et al. disclose the use of an ultraviolet-curable adhesive for attaching a strain relief and hub to a catheter shaft. Although Ferrara et al. do disclose an ultraviolet-curable material, they do not appear to disclose that their layer of adhesive has any structurally distinct portions. In particular, Ferrara et al. do not appear to teach or disclose that their adhesive has portions that are cured to differing extents so as to define structurally distinct portions or that different portions of the adhesive have different flexibilities. Instead, all of the adhesive in Ferrara et al. is cured to the same extent so as to define a singular, homogenous structure. Ferrara et al., therefore, cannot anticipate multiple structurally distinct portions of a selectively curable material that are distinguished by their respective amounts of curing.

MPEP §2131 states that in order for a reference to anticipate a claim, the reference must teach every element of the claim. Ferrara et al. have failed to disclose a first layer of selectively curable material that includes first and second portions that are cured to different extents. Because they have failed to disclose or teach a first layer having multiple, structurally distinct,

cured regions, Ferrera et al. have failed to meet this standard. Accordingly, Ferrera et al. cannot anticipate claim 1 or claims 4-6 depending therefrom.

On page 2 of the February 20, 2004 Advisory Action, the Examiner indicted that MPEP §2112.02 (sic, §2113) states that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process”. MPEP §2113 quoting In re Thorpe, 777 F. 2d. 695, 698 (Fed. Cir. 1985). The Examiner appears to saying that claim 1 is a product-by-process claim and that Ferrera et al. anticipates claim 1 because they disclose the same product, albeit made by a different process. Appellant completely disagrees.

As described above, the word “cured” is used as an adjective so as to more clearly indicate that the first layer includes a first layer having multiple regions that are structurally distinguishable by their differential levels of curing. Ferrera et al. fail to teach a first layer of selectively curable material that discloses structurally distinct regions. Therefore, even if claim 1 was a product-by-process claim, Ferrera et al. could not anticipate claim 1 because Ferrera et al. do not teach the product. Additionally, because claim 1 recites structural and not method limitations, claim 1 is not a product-by-process claim. Therefore, whether or not Ferrera et al. disclose another method by which the same product can be formed is a moot point. The plain and simple fact is that in order to anticipate a claim, the cited reference must disclose or teach each and every claim element. As stated above, Appellant’s claim 1 clearly recites structurally different regions of selectively curable first layer. Ferrera et al. fail to disclose these structurally

distinct regions. Accordingly, the rejection of claims 1 and 4-6 over Ferrera et al. is improper and should be withdrawn in due course.

B. Claims 1 and 4-6 are patentable over Derbin et al. (U.S. Patent No. 6,562,021).

As described above, claim 1 recites that the first layer has structurally distinguishable first and second portions. In a manner very similar to Ferrera et al., Derbin et al. disclose the use of an ultraviolet-curable adhesive for attaching a strain relief and hub to a catheter shaft. Like Ferrera et al., Derbin et al. do not appear to disclose that the adhesive includes structurally distinct first and second portions. More particularly, Derbin et al. do not appear to disclose that the adhesive includes first and second portions that are structurally differentiated by their level of curing and by their flexibility. Because Derbin et al. fail to disclose a structural element of claim 1, Derbin et al. cannot anticipate claim 1. Based on this distinction, claims 4-6 are also not anticipated because they depend from claim 1 and because they add significant elements to distinguish them further from the prior art.

C. Claims 1-6 are patentable over Berg et al. (U.S. Patent No. 5,897,537).

As described above, claim 1 recites that the first layer has structurally distinguishable first and second portions. Like Ferrera et al. and Derbin et al., Berg et al. only appear to disclose the use of an ultraviolet-curable material. Berg et al. disclose that the ultraviolet-curable material may be part of a layer of filler material. Please see, for example, Berg et al. at column 9, line 66 through column 10, line 4. Berg et al., however, do not disclose that the filler material includes structurally distinct portions. More particularly, Berg et al. do not disclose that the filler material includes first and second portions that are structurally differentiated by their level of curing and by their flexibility. Because Berg et al. fail to disclose a structural element of claim 1, Berg et al. cannot anticipate claim 1. Based on this distinction, claims 2-6 are also not anticipated, because

they depend from claim 1 and because they add significant elements to distinguish them further from the prior art.

D. Claims 7-10 are patentable over Ferrera et al. in view of Derbin et al. or Berg et al.

In light of the above remarks, Appellant respectfully submits that claim 1 is in condition for allowance based on the failures of all three cited references to disclose the structural limitations of claim 1. Because claims 7-10 depend from claim 1, they are also allowable based on these remarks and because they add significant elements to distinguish them further from the prior art. Accordingly, Appellant respectfully requests that this rejection be withdrawn and that claim 7-10 be allowed in due course.

IX. CONCLUSION

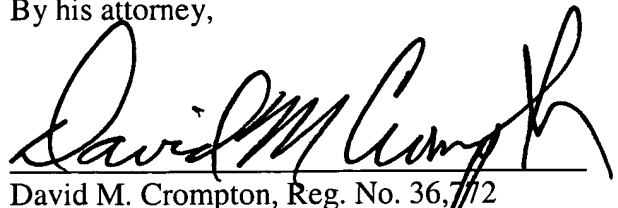
For the reasons stated above, the rejection of claims 1-10 under 35 U.S.C. §§102(b), 102(e), and 103(a) should be reversed.

Respectfully submitted,

Henry J. Pepin

By his attorney,

Date: 5/27/04



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X. APPENDIX OF CLAIMS

1. A support member used to form at least a portion of a catheter shaft, comprising:
an inner member defining an outer surface thereon; and
a first layer disposed over at least a portion of the outer surface of the inner member, the first layer including a selectively curable material, the first layer further comprising first and second portions of the selectively curable material;
wherein the first portion of the selectively curable material is at least partially cured and the second portion of the selectively curable material is either uncured or cured to a lesser degree than the first portion of the selectively curable material;
wherein the first portion of the selectively curable material has a first flexibility and the second portion of the selectively curable material has a second flexibility; and
wherein the first flexibility and second flexibility are different.
2. The support member in accordance with claim 1, wherein the first layer comprises epoxy.
3. The support member in accordance with claim 2, wherein the first layer is ultraviolet-curable.
4. The support member in accordance with claim 1, further comprising a second layer disposed over at least a portion of the first layer, wherein the second layer includes a first wire ribbon.

5. The support member in accordance with claim 4, wherein the first wire ribbon is wound in a helical pattern in a first direction.

6. The support member in accordance with claim 5, further comprising a third layer disposed over at least a portion of the second layer, wherein the third layer includes a selectively curable material, the selectively curable material at least partially cured at desired portions thereof to alter the flexibility of the support member at the desired portions.

7. The support member in accordance with claim 6, wherein the third layer is an ultraviolet-curable epoxy.

8. The support member in accordance with claim 6, further comprising a fourth layer disposed over at least a portion of the third layer, wherein the fourth layer comprises a second wire ribbon.

9. The support member in accordance with claim 8, wherein the second wire ribbon is wound in a helical pattern in a second direction opposite the first direction.

10. The support member in accordance with claim 8, further comprising a fifth layer disposed over at least a portion of the fourth layer, wherein the fifth layer comprises a polymer.

Claims 11-26. (withdrawn)

XI. APPENDIX OF AUTHORITIES CITED

In re Thorpe, 777 F. 2d. 695, 698 (Fed. Cir. 1985).